REMARKS

Claims 3, 4, 6-8, 35-41, 60, 61, 66-69, and 102-121 are pending. Claim 6 is amended herein. Support for the amendments to claims is found throughout the Specification and claims, as filed, and no new matter is presented by the amendment.

Favorable reconsideration in light of the amendments are remarks which follow a respectfully requested.

1. Double Patenting

Claims 103-106 are provisionally rejected as claiming the same invention as claims 111-114 of copending Application No. 10/984,450.

Claims 3, 4, 6-8, 35-41, 60-61, 66-69, 107-121 are provisionally rejected in view of copending Application No. 10/984,450 on the ground of nonstatutory obviousness-type double patenting.

Applicant acknowledges notice of the provisional obviousness type double patenting rejections and will address the rejections upon indication of allowable subject matter.

2. 35 U.S.C. §102 Rejections

Claims 3, 6-8, 35, 60, 61, 66-69, 102, 116, 117, 119, 120, and 121 are rejected under 35 U.S.C. §102(b) as being anticipated by Cevc (US patent 6,165,500).

Applicants respectfully traverse.

Applicants teach methods, kits, and devices for controlling the flux of penetrants across an adaptable semi-permeable porous barrier. These methods, kits, and devices make it possible to specifically and predictably control the rate of transcutaneous drug delivery.

Prior to applicants' teaching, it was believed that the channels in the skin through which highly deformable droplets migrate possess properties that are sufficiently constant, and that the relative bio-availability of different drugs in the blood after application to the skin is fairly constant. It was further believed that pore distribution depends little on the nature of the penetrant or the drug, and that the dose merely impacts the depth of penetrant and drug distribution.

Applicants unexpectedly discovered, contrary to previous beliefs, that the rate of penetrant transport across the skin barrier can be controlled specifically and predictably. According to applicants, the flux of penetrants across the skin barrier can be controlled based on the dose of penetrants. Selection of the dose of penetrants above a certain threshold and in a sufficiently wide range not only affects the drug/penetrant distribution, but also determines the rate of penetrant transport across the barrier. This provides significant improvements in the delivery of drugs through the skin.

US '500 is directed to preparations for the transport of agents through permeability barriers and constrictions. However, US '500 at least does not teach or suggest a method for controlling the delivery of drugs through the skin or the flux of penetrants through the skin. Nowhere in US '500 is it even recognized that it could be possible to specifically and predictably control to rate of transcutaneous drug delivery using the described preparations. Further, US '500 does not teach or suggest that the selection of the penetrant dose has anything to do with the flux of the penetrant through the skin.

In sum, Applicants teach methods, kits, and devices for controlling the flux of penetrants across the skin. Applicants unexpectedly found that the use of different amounts of identical formulations will produce a specific and predictable controlled rate of transcutaneous drug delivery. This finding is counter-intuitive and has not been taught or suggested by the prior art. On the contrary, one of skill in the art would have thought that the flux across a semi-permeale barrier follows the first law of diffusion (Fick's law) and is governed by the characteristics of the formulation rather than by the volume of penetrant. This is in contrast to Applicants' teaching that

penetrant concentration in a corresponding formulation does not govern but, rather, the applied amount of penetants is the most important factor of barrier transport.

3. 35 U.S.C. §112 Rejections

Claim 6 is rejected under 35 U.S.C. §112, second paragraph.

To expedite prosecution, applicants have amended the claim. Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

Applicant respectfully requests early consideration and allowance of the subject application.

Applicants believe that additional fees are not required in connection with the consideration of the within matter. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105.**

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

Respectfully submitted,

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